How outsourcing lifecycle maintenance activities led to the development of a new pipeline

A CLIENT SUCCESS STORY

Situation

A mid-sized biopharma company had a small in-house regulatory team, including several publishing resources, managing their RX portfolio.

Challenge

The company needed to free up internal resources to expand its new product pipeline and wanted a seamless transition of lifecycle maintenance activities globally for 16 products marketed in over 50 markets.

Solution

Parexel successfully integrated into the company's organization and took over the delivery of the RX portfolio for both regulatory affairs and publishing, a truly embedded regulatory function. Services included but were not limited to:

- Renewals and Repeat use procedures
- Publishing – pre (IND and NDAs) and post-approval
- Ad-hoc regulatory intelligence and strategic support in Russia and EAEU region, China, South Korea, the United States, and the UK
- Direct Health authority interactions with MHRA, HPRA, and EMA on behalf of the company
- Periodic reporting (PSURs) and follow up for Safety variations
- Local agency database updates

Results

Our team provided 'round the clock' publishing support of up to 21 hours a day. We supported the company with regulatory intelligence and strategy in local markets where they had no presence.

The successful integration enabled the company's in-house staff to focus on expanding their new product pipeline, and lifecycle publishing led to further publishing of new MAAs, NDAs, and INDs.

Find out more at:
www.parexel.com/regulatory-outsourcing

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